62. (Amended) An isolated polypeptide encoded by a nucleic acid molecule having a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 but with at least one modification that is a C-terminal truncation or an N-terminal truncation, provided that the polypeptide does not further comprise the amino acid sequence of SEQ ID NO: 22, and wherein the polypeptide upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5.

REMARKS

The Examiner indicated that claims 9, 13-16, 40-42, 46, 47, and 57-62 were pending at the issuance of the instant Office Action. Claims 9, 13-16, 57, 58, 61, and 62 have been amended, and claims 40-42 have been canceled. The amendments to the claims are fully supported by the specification. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Rejections of claims 9, 14, 15, 40-42, 46, 47, and 57-62 under 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 9, 14, 15, 40-42, 46, 47, and 57-62 under 35 U.S.C. § 112, first paragraph, because the specification purportedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. The Examiner takes the position that, given the broadest reasonable interpretation, the breadth of the claims in the present application encompasses any and all isolated polypeptides. More specifically, the Examiner contends that because claim 9 is not limited to the polynucleotide sequence of SEQ ID NO: 4, claim 9 encompasses any polypeptide produced by a process of culturing a host cell containing a vector encoding the polypeptide, wherein said vector comprises at least two contiguous residues of the polynucleotide sequence set forth in SEQ ID NO: 4. The Examiner also contends that claims 57 and 59-61 are similarly drawn to the vast majority of polypeptides. The Examiner further contends that because claim 14 only requires the claimed polypeptides to comprise an amino acid sequence of an ortholog of the polypeptide of SEQ ID NO: 5, claim 14 encompasses any polypeptide having an amino acid sequence comprising at least

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two contiguous amino acids of the amino acid sequence of an ortholog of the polypeptide of SEQ ID NO: 5. In addition, the Examiner contends that because claim 15 permits any number of substitutions or truncations, claim 15 encompasses virtually every polypeptide having an activity shared by the polypeptide of SEQ ID NO: 5, including immunogenicity. The Examiner also contends that claims 58-60 and 62 are similarly drawn to virtually every polypeptide.

Applicants have amended claim 9 to recite "[a] polypeptide having the amino acid sequence as set forth in SEQ ID NO. 5." Applicants contend that claim 9, as amended, no longer encompasses the vast majority of polypeptides, and respectfully request that this ground of rejection be withdrawn.

Applicants have amended claim 14 to recite "the amino acid sequence for an ortholog of SEQ ID NO: 5." Applicants contend that claim 14, as amended, no longer encompasses any polypeptide having an amino acid sequence comprising at least two contiguous amino acids of the amino acid sequence of an ortholog of the polypeptide of SEQ ID NO: 5, and respectfully request that this ground of rejection be withdrawn.

Applicants have amended claim 57 to clearly indicate that the produced polypeptide is encoded by the nucleic acid molecule introduced into the host cell, that the produced polypeptide is a fragment of at least about 25 amino acid residues, and that the produced polypeptide upon injection into an animal produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5. Applicants contend that claim 57, as amended, does not encompass the vast majority of polypeptides, and respectfully request that this ground of rejection be withdrawn.

Applicants have amended claim 58 to clearly indicate that the produced polypeptide is has the amino acid sequence as set forth in SEQ ID NO: 5 but with at least one modification that is a C-terminal truncation or an N-terminal truncation, and upon injection into an animal the produced polypeptide produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5. Applicants contend that claim 58, as amended, does not encompass the vast majority of polypeptides, and respectfully request that this ground of rejection be withdrawn.

Finally, Applicants have amended claims 15, 61, and 62 to recite that the isolated polypeptide "upon injection into an animal produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5." Applicants contend that claims 15, 61, and 62, as amended, do not encompass the vast majority of polypeptides, and respectfully request that these grounds of rejection be withdrawn.

The Examiner also takes the position that because the effect of a particular amino acid substitution in a polypeptide variant on the structure or function of that polypeptide variant cannot be

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accurately predicted, one with skill in the art cannot make and use the claimed invention without undue experimentation. More specifically, the Examiner contends that the specification does not provide sufficient guidance or direction or exemplification to enable the skilled artisan to immediately know which amino acid residues are important to the activity or function of the polypeptide of SEQ ID NO: 5, and that one of ordinary skill in the art could not know or predict at which positions conservative amino acid substitutions in the polypeptide sequence might be made without adversely affecting the activity or function of the polypeptides encompassed by the claims.

Although Applicants disagree with the Examiner's position, Applicants have amended claims 15, 58, and 62 in order to expedite prosecution of the instant application. Applicants contend that the amendments to claims 15, 58, and 62 overcome this ground of rejection.

The Office Action also asserts a rejection of claims 40-42 and 47 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The Examiner takes the position that the specification does not teach any use other than in formulating pharmaceutical compositions for the chemically derivatized polypeptides of claims 40-42. The Examiner also takes the position that the specification does not teach any use other than in formulating pharmaceutical compositions for the fusion polypeptides comprising a Secs-1 polypeptide fused to an IgG constant domain or fragment thereof of claim 47.

In order to expedite prosecution of the instant application, Applicants have canceled claims 40-42 without prejudice or disclaimer, rendering rejection of these claims moot. With respect to claim 47, Applicants contend that the specification in fact does teach uses other than in formulating pharmaceutical compositions for the fusion polypeptides comprising a Secs-1 polypeptide fused to an IgG constant domain or fragment thereof. For example, the specification teaches on page 93, lines 29-31 that an IgG constant domain can be used as an epitope tag in a Secs-1 fusion polypeptide in order to detect Secs-1 polypeptide expression by Western blot analysis following expression of the Secs-1 fusion polypeptide in mammalian cells. As the specification teaches uses other than in formulating pharmaceutical compositions for the fusion polypeptides comprising a Secs-1 polypeptide fused to an IgG constant domain or fragment thereof, Applicants respectfully request that this ground of rejection be withdrawn.

The Office Action also asserts a rejection of claims 9, 15, 40-42, 46, 47, and 57-62 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner takes the position that claims 9, 15, 40-42, 46, 47, and 57-62 are drawn to a very broad genus of polypeptides encompassing the vast majority of polypeptides and that the disclosure of two members of the claimed genus of polypeptides (SEQ ID NO: 2 and SEQ ID NO: 5) is not sufficiently representative of claimed genus.

As discussed above, Applicants have amended claims 9, 14, 15, 57, 58, 61, and 62. Applicants contend that claims 9, 14, 15, 57, 58, 61, and 62, as amended, are no longer drawn to a very broad genus of polypeptides encompassing the vast majority of polypeptides, and respectfully request that this ground of rejection be withdrawn.

With respect to claims 57 and 59-61, the Examiner takes the position that there does not appear to be sufficient antecedent basis in the specification for the terms "a region of the nucleotide sequence of SEQ ID NO: 4" and "a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755," as recited in claims 57 and 61.

Applicants contend that there is indeed sufficient antecedent basis in the specification for the terms. Claim 57 is dependent on claim 9, which, as originally filed, recited [a] polypeptide produced by the process of Claim 8." Claim 8, in turn, depended on claim 5, which depended on claim 4. Claim 4, as originally filed, recited "[a] vector comprising the nucleic acid molecule of any of Claims 1, 2, or 3." Claim 57, therefore, is directed to a polypeptide produced by the process of claim 8 in the host cell of claim 5, which contains the vector of claim 4, which in turn comprises the nucleic acid molecule of claim 2. Claim 61, on the other hand, is dependent on claim 16, which, as originally filed, recited "[a]n isolated polypeptide encoded by the nucleic acid molecule of any of Claims 1, 2, or 3, wherein the polypeptide has an activity of the polypeptide set forth in either SEQ ID NO: 2 or SEQ ID NO: 5." More specifically, claim 61 is directed to an isolated polypeptide encoded by the nucleic acid molecule of claim 2. Because claim 2(c), as originally filed, recited "a region of the nucleotide sequence of either SEQ ID NO: 1 or SEQ ID NO: 4" and "a region of...the DNA insert in ATCC Deposit Nos. PTA-1753 and PTA-1755," Applicants contend that there is sufficient antecedent basis in the specification for the terms "a region of the nucleotide sequence of SEQ ID NO: 4" and "a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755," and respectfully request that this ground of rejection be withdrawn.

Applicants respectfully contend that rejections based on 35 U.S.C. § 112, first paragraph,

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have been overcome by amendment, traversed by argument, or mooted by cancellation of the rejected claims, and request that the Examiner withdraw all rejections made on this basis.

2. Rejections of claims 9, 13-16, 40-42, 46, 47, and 57-62 under 35 U.S.C. § 112, second paragraph

The Office Action asserts a rejection of claims 9, 13-16, 40-42, 46, 47, and 57-62 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner takes the position that claims 14-16, 40-42, 46, 47, and 57-62 are vague and indefinite for reciting "has an activity," because it is unclear to which activity the claims refer, and therefore, it cannot be ascertained whether the claimed polypeptides have the required activity.

Applicants have amended claims 15, 16, 57, 58, 61, and 62 to delete the phrase "has an activity." Claims 15, 16, 57, 58, 61, and 62 now specify that the claimed polypeptide, upon injection into an animal, produce an antibody that binds to the polypeptide set forth in SEQ ID NO: 5. Applicants contend that claims 15, 16, 57, 58, 61, and 62, as amended, satisfy the definiteness requirement of § 112, second paragraph, and therefore, respectfully request that the rejection on this ground be withdrawn.

The Examiner also takes the position that claims 9, 13, 16, 40-42, 46, 47, 57, and 59-61 are indefinite for reciting the phrase "the DNA insert in ATCC Deposit No. PTA-1755," because it is not clear to which DNA insert the claims refer. The Examiner also contends that it is not absolutely evident that the cDNA molecule encoding the polypeptide of SEQ ID NO: 5 is the DNA insert to which the claims refer, or if the DNA insert to which the claims refer has the polynucleotide sequence set forth in SEQ ID NO: 4.

As suggested by the Examiner in the instant office action, Applicants have amended claims 9, 13, 16, 57, and 61 to recite "the DNA insert in ATCC Deposit No. PTA-1755 wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5." Applicants contend that claims 9, 12, 16, 57, and 61, as amended, satisfy the definiteness requirement of § 112, second paragraph, and therefore, respectfully request that the rejection on this ground be withdrawn.

The Examiner also takes the position that claims 57 and 59-61 are indefinite for reciting the phrases "a region of the nucleotide sequence of SEQ ID NO: 4" and "a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755," because it cannot be ascertained to

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which region of the nucleotide sequence set forth in SEQ ID NO: 4 or to which region of the nucleotide sequence of the DNA insert in the deposit the claims refer.

Applicants disagree with the Examiner's position that the phrases "a region of the nucleotide sequence of SEQ ID NO: 4" and "a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755" are indefinite. Applicants contend that one of ordinary skill in the art would readily understand that the phrase "a region of the nucleotide sequence" would refer to a fragment or portion of the entire nucleotide sequence of SEQ ID NO: 4 or the DNA insert in ATCC Deposit No. PTA-1755. Applicants also contend that one of ordinary skill in the art would readily understand that claims 57 and 61 are directed to polypeptide fragments of at least about 25 amino acids encoded by "a region of the nucleotide sequence of SEQ ID NO: 4" or "a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755," wherein the polypeptide fragment upon injection into an animal produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5. Applicants, therefore, contend that claims 57 and 61 satisfy the definiteness requirement of § 112, second paragraph, and therefore, respectfully request that the rejection on this ground be withdrawn.

The Office Action also asserts a rejection of claims 9, 14, 15, and 57-62 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which Applicants regard as their invention. The Examiner takes the position that because claims 9, 15, and 57-62 encompass virtually every polypeptide, provided that the polypeptide is immunogenic, claims 9, 15, and 57-62 fail to correspond in scope with that which Applicants regard as the invention. The Examiner also takes the position that Applicants' statements in Paper No. 12 indicate that the invention is different from what is defined in claims 9, 14, and 15, because the claims do not require the claimed polypeptide to be encoded by a nucleic acid sequence comprising the entire coding sequence of the amino acid sequence of SEQ ID NO: 5.

Applicants disagree with the Examiner's characterization of Applicants' statements in Paper No. 12. Applicants, in arguing that neither the FAPESP/LICR Human Cancer Genome Project nor Hillier *et al.* teach the amino acid sequence of Secs-1 polypeptide, were merely discussing what those references disclosed, and were not defining the claimed invention. It is readily apparent that neither the FAPESP/LICR Human Cancer Genome Project nor Hillier *et al.* teach any amino acid sequence. Moreover, in stating that many isolated polypeptides lack an activity of the polypeptide set forth in SEQ ID NO: 5, Applicants were referring to the particular biological activity of the polypeptide set forth in SEQ ID NO: 5, and not properties common to the vast majority of

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polypeptides (such as immunogenicity). Applicants suggest that the alternative language of claim 14 supports, rather than contradicts, Applicants' distinction between activity and antigenicity. However, in an effort to expedite prosecution of the instant application, Applicants have deleted the phrase "has an activity" from the claims. For these reasons, Applicants contend that claims 9, 14, 15, and 57-62 fail to correspond in scope with that which Applicants regard as the invention, and respectfully request that this ground of rejection be withdrawn.

Applicants respectfully contend that rejections based on 35 U.S.C. § 112, second paragraph, have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

3. Rejections of claims 9, 13-16, and 57-62 under 35 U.S.C. § 102

The Office Action asserts a rejection of claims 9, 13, 14, 16, 57, and 59-61 under 35 U.S.C. § 102(a), as being anticipated by the FAPESP/LICR Human Cancer Genome Project (GenBank EST Database Accession No. AW351839). The Examiner takes the position that the FAPESP/LICR Human Cancer Genome Project teach a polypeptide that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5. The Examiner also takes the position that because the polypeptide taught by the FAPESP/LICR Human Cancer Genome Project has the same amino acid sequence as the polypeptide of SEQ ID NO: 5, the polypeptide taught by the FAPESP/LICR Human Cancer Genome Project will have an activity of the polypeptide of SEQ ID NO: 5. Applicants traverse this rejection.

With regard to the nucleotide sequence disclosed in GenBank Accession No. AW351839, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 establishing invention of the subject matter of the claims rejected under 35 U.S.C. § 102(a) prior to the effective date of the reference on which the rejection is based. Applicants contend that the Declaration Pursuant to 37 C.F.R. § 1.131, filed February 11, 2002, is sufficient to overcome the rejection of claims 9, 13, 14, 16, 57, and 59-61 under 35 U.S.C. § 102(a) as being anticipated by the FAPESP/LICR Human Genome Project. While the nucleotide sequence disclosed by the FAPESP/LICR Human Genome Project *may* have been submitted sometime in 1999 (as suggested by the entry "Unpublished (1999)" appearing at line 13 of the reference), Applicants contend that the sequence was not *accessible to the public* until February 1, 2000 (as indicated by the entry "01-FEB-2000" appearing at line 1 of the reference), and therefore, was not *publicly known* until that date. The phrase "known or used" in 35

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U.S.C. § 102(a) means "Means Publicly Known or Used." MPEP § 2132. "The statutory language 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." *Carella v. Starlight Archery*, 804 F.2d 135 (Fed. Cir. 1986). Applicants respectfully contend that "knowledge" of one or even a few individuals does not satisfy the requirement of 35 U.S.C. § 102(a) that the invention be accessible to the public, according to the plain language of the M.P.E.P. Therefore, for the purposes of antedating the FAPESP/LICR Human Genome Project, Applicants contend that the Declaration is sufficient.

Moreover, Applicants contend that the document accompanying the Declaration sufficiently asserts a reduction to practice of the claimed invention before February 1, 2000. Specifically, paragraph 4 of the Declaration states that:

> Accompanying this Declaration is a copy of a sequence match obtained by us before February 1, 2000 documenting a reduction to practice of our invention. This match was obtained following a comparison of a nucleic acid sequence derived from the amino acid sequence of a secreted polypeptide isolated from squamous cell and colorectal carcinoma cells to a proprietary EST database.

The specification states (page 84, line 27 to page 85, line 1) that:

> Using a proteomic-based approach, a novel protein was isolated from conditioned media obtained from squamous cell and colorectal carcinoma cell lines. The approach utilized in isolating this protein suggests that it is a naturally secreted product. The amino acid sequence of the isolated protein was determined and found to share sequence identity with EST sequences present in both GenBank and proprietary (Amgen dbEST) databases.

Applicants contend that when the nucleotide sequence set forth in SEQ ID NO: 4 was obtained, the claimed invention was reduced to practice. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991). As described in the Declaration, and in the specification, that nucleotide sequence was obtained when a comparison of the amino acid sequence derived from a protein obtained from squamous cell and colorectal carcinoma cell lines was compared with a proprietary EST database. The sequence match accompanying the Declaration establishes that Applicants identified and possessed the nucleotide sequence of the claimed invention, and therefore had reduced the claimed invention to practice, before February 1, 2000. Applicants, therefore, contend that the FAPESP/LICR Human Genome Project does not anticipate claims 9, 13, 14, 16, 57, and 59-61 under 35 U.S.C. § 102(a), and therefore, respectfully request that this rejection be withdrawn.

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The Office Action also asserts a rejection of claims 9, 14, 15, and 57-62 under 35 U.S.C. § 102(b), as being anticipated by Hillier *et al.* (GenBank EST database Accession No. AA422178). The Examiner takes the position that Hillier *et al.* teach a polypeptide that is 100% identical to that amino acid sequence set forth in SEQ ID NO: 5 over the region spanning from amino acid residues 1 to 76, and therefore, Hillier *et al.* teach a polypeptide that is truncated at its C-terminus, encoding a fragment of SEQ ID NO: 5 comprising at least about 25 amino acid residues. The Examiner also takes the position that because the polypeptide taught by Hillier *et al.* has the same amino acid sequence as the polypeptide of SEQ ID NO: 5, the polypeptide taught by Hillier *et al.* will have an activity of the polypeptide of SEQ ID NO: 5.

Applicants contend that because the nucleotide sequence disclosed by Hillier *et al.* lacks the nucleotide found at position 258 in the nucleotide sequence of SEQ ID NO: 4 (as shown in Appendix A), one of ordinary skill in the art would determine that the deduced polypeptide encoded by the nucleic acid molecule disclosed by Hillier *et al. differs* from the polypeptide set forth in SEQ ID NO: 5 at positions 77-81 and possesses an *additional* 17 amino acids at its C-terminal end. As the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* is *longer* than the polypeptide set forth in SEQ ID NO: 5, Applicants contend that the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* cannot anticipate a polypeptide fragment of at least about 25 amino acid residues of the polypeptide set forth in SEQ ID NO: 5. In other words, the genus of variants defined by claims 14, 15, 57, 58, 61, and 62 (in which the largest member of the genus is a polypeptide of no more than 80 amino acids) does not encompass the nucleic acid molecule of Hillier *et al.* (which would encode a polypeptide of 98 amino acids). However, in an effort to expedite prosecution and more clearly define the polypeptides of claims 14, 15, 57, 58, 61, and 62, Applicants have added the limitation that the polypeptide not further comprise the amino acid sequence of SEQ ID NO: 22 (wherein the amino acid sequence of SEQ ID NO: 22 is E-S-H-R-C-S-T-P-K-A-R-L-Q-T-A-E-N-L-M-P-G-T), thereby excluding polypeptides comprising the non-naturally occurring portion of the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* Applicants contend that Hillier *et al.* does not anticipate amended claims 9, 14, 15, and 57-62 under 35 U.S.C. § 102(b), and therefore, respectfully request that this rejection be withdrawn.

Applicants respectfully contend that rejections based on 35 U.S.C. § 102 have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on these grounds.

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4. Rejections of claims 9, 13-16, 17, 46, 57, and 59-61 under 35 U.S.C. § 103

The Office Action asserts a rejection of claims 9, 13, 14, 16, 17, 46, 57, and 59-61 under 35 U.S.C. § 103(a), as being unpatentable over the FAPESP/LICR Human Cancer Genome Project (GenBank EST Database Accession No. AW351839). The Examiner takes the position that it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the nucleic acid molecule of the FAPESP/LICR Human Cancer Genome Project so that the modified nucleic acid molecule would encode a fusion polypeptide. Applicants traverse this rejection.

As discussed in section 3 above, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 establishing invention of the subject matter of claims 9, 13, 14, 16, 17, 46, 57, and 59-61 prior to the effective date of the FAPESP/LICR Human Cancer Genome Project. Therefore, Applicants contend that the claims are not obvious under 35 U.S.C. § 103 with respect to this reference, and request the Examiner withdraw this rejection.

The Office Action also contains a rejection of claims 9, 14, 15, 46, and 57-62 under 35 U.S.C. § 103(a), as being unpatentable over Hillier *et al.* (GenBank EST database Accession No. AA422178). The Examiner takes the position that it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the nucleic acid molecule of Hillier *et al.* so that the modified nucleic acid molecule would encode a fusion polypeptide.

As discussed in section 3 above, the deduced polypeptide encoded by the nucleic acid molecule disclosed by Hillier *et al.* differs from the polypeptide set forth in SEQ ID NO: 5 at positions 77-81 and possesses an additional 17 amino acids at its C-terminal end. Applicants contend that because the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* is longer than the polypeptide set forth in SEQ ID NO: 5, the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* cannot anticipate a polypeptide fragment of at least about 25 amino acid residues of the polypeptide set forth in SEQ ID NO: 5. However, in an effort to expedite prosecution and more clearly define the polypeptides of claims 14, 15, 57, 58, 61, and 62, Applicants have added the limitation that the polypeptide not further comprise the amino acid sequence of SEQ ID NO: 22 (wherein the amino acid sequence of SEQ ID NO: 22 is E-S-H-R-C-S-T-P-K-A-R-L-Q-T-A-E-N-L-M-P-G-T), thereby excluding polypeptides comprising the non-naturally occurring portion of the deduced polypeptide encoded by the nucleic acid molecule of Hillier *et al.* Applicants

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therefore respectfully contend that amended claims 9, 14, 15, and 57-62 are not obvious under 35 U.S.C. § 103 with respect to Hillier *et al.*, and request the Examiner withdraw this rejection.

Applicants respectfully contend that rejections based on 35 U.S.C. § 103 have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

Dated: July 23, 2002

By: _____
Kevin E. Noonan, Ph.D.
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AMENDMENTS TO THE CLAIMS

Marked Up Versions of Amended Claims under 37 C.F.R. 1.121(c)(1)(ii)

9. (Twice Amended) A polypeptide having the amino acid sequence as set forth in SEQ ID NO. 5 produced by a process comprising:

(a) culturing a host cell containing a vector comprising a nucleic acid having a nucleotide sequence

(i) as set forth in SEQ ID NO. 4;

(ii) of the DNA insert in ATCC Deposit No. PTA-1775, wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5; or

(iii) that encodes a polypeptide having ~~an~~ the amino acid sequence as set forth in SEQ ID NO. 5;

under conditions suitable to express the polypeptide; and optionally

(b) isolating the polypeptide from the culture.

13. (Twice Amended) An isolated polypeptide comprising:

(a) the amino acid sequence as set forth in SEQ ID NO: 5; or

(b) the amino acid sequence encoded by the DNA insert in ATCC Deposit No. PTA-1755, wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5.

14. (Twice Amended) An isolated polypeptide comprising:

(a) the amino acid sequence as set forth in SEQ ID NO: 6, optionally further comprising an amino-terminal methionine;

(b) ~~an~~ the amino acid sequence for an ortholog of SEQ ID NO: 5; or

(c) a fragment of the amino acid sequence set forth in SEQ ID NO: 5 comprising at least about 25 amino acid residues, wherein the fragment ~~has an activity of~~ upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5, ~~or is antigenic~~ and provided that the fragment does not further comprise the amino acid sequence of SEQ ID NO: 22.

15. (Twice Amended) An isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 5 but with at least one modification that is a ~~conservative amino acid~~

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~~substitution,~~ C-terminal truncation~~,~~ or an N-terminal truncation, provided that the polypeptide does not further comprise the amino acid sequence of SEQ ID NO: 22, wherein the polypeptide ~~has an activity of~~ upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5.

16. (Twice Amended) An isolated polypeptide encoded by a nucleic acid molecule comprising:

(a) the nucleotide sequence as set forth in SEQ ID NO: 4;

(b) the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755, wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5; or

(c) a nucleotide sequence encoding the polypeptide as set forth in SEQ ID NO: 5;

wherein the polypeptide ~~has an activity of~~ upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5.

57. (Amended) A polypeptide produced by a process comprising:

(a) culturing a host cell containing a vector comprising a nucleic acid molecule having a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755 wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5, but does not further comprise the amino acid sequence of SEQ ID NO: 22, wherein the nucleic acid molecule encodes the polypeptide which is produced, ~~a~~ the polypeptide is a fragment of at least about 25 amino acid residues, and wherein the polypeptide ~~fragment has an activity of the encoded~~ upon injection into an animal produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5, under suitable conditions to express the polypeptide, and optionally

(b) isolating the polypeptide from the culture.

58. (Amended) A polypeptide produced by a process comprising:

(a) culturing a host cell containing a vector comprising a nucleic acid molecule having a nucleotide sequence encoding ~~a~~ the polypeptide which is produced, the polypeptide ~~having~~ has the amino acid sequence as set forth in SEQ ID NO: 5 but with at least one modification that is a ~~conservative amino acid substitution,~~ C-terminal truncation~~,~~ or an N-terminal truncation, provided

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that the polypeptide does not further comprise the amino acid sequence of SEQ ID NO: 22, and wherein the polypeptide ~~has an activity of~~ upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5, under suitable conditions to express the polypeptide, and optionally

(b) isolating the polypeptide from the culture.

61. (Amended) An isolated polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or a region of the nucleotide sequence of the DNA insert in ATCC Deposit No. PTA-1755 wherein the DNA insert encodes the polypeptide as set forth in SEQ ID NO: 5, but does not further comprise the amino acid sequence of SEQ ID NO: 22, wherein ~~the nucleic acid molecule encodes a~~ the polypeptide is a fragment of at least about 25 amino acid residues, and wherein the polypeptide ~~fragment has an activity of the encoded~~ upon injection into an animal produces an antibody that binds to the polypeptide as set forth in SEQ ID NO: 5.

62. (Amended) An isolated polypeptide encoded by a nucleic acid molecule having a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 but with at least one modification that is a ~~conservative amino acid substitution,~~ C-terminal truncation, or an N-terminal truncation, provided that the polypeptide does not further comprise the amino acid sequence of SEQ ID NO: 22, and wherein the polypeptide ~~has an activity of~~ upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5.

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